K092933

510(k) SUMMARY

JAN 14 2010

REDENT NOVA's SAF (Self Adjusting File)

Submitter's Name, Address, Telephone Number, Contact Person: and Date Prepared

Hogan & Hartson

Phone: 202 637 5600
Facsimile: 202 637 5910

Contact Person: Jonathan S. Kahan

Date Prepared: December 14, 2009

Name of Device and Name/Address of Sponsor:

SAF (Self Adjusting File)

Redent Nova Ltd.

15 Hataasia street

P.O.B 4159

Ra'anana

43000, Israel

Common or Usual Name

SAF (Self Adjusting File)

Classification Name

Name: Dental Handpiece and accesories

Product code: EFB

Classification regulation: 872.4200

Class: I

Panel: Dental

K092933

Predicate Devices

ProTaper – Dentsply Tulsa Dental (510(k) exempt)

Quantec Series 2000 – Tyco Dental (K962031)

Profile 29 – Dentsply Tulsa Dental (K933582)

Intended Use / Indications for Use

The Self Adjusting file (SAF) is a mechanically operated endodontic file to be used for cleaning and shaping of root canals, as part of the procedure of root canal treatment.

Technological Characteristics

The ReDent SAF is an endodontic file that is indicated for use in root canal treatment for cleaning and shaping of the root canal. The file portion of the SAF consists of a metal lattice hollow cylinder and is constructed from medical grade nickel-titanium-alloy. The file's cylindrical lattice structure permits compression when inserted into the root canal followed by gradual radial expansion to fill the root canal profile. The file is surface treated by sandblasting, enabling it to file dentin from the canal's interior surface.

The SAF is available in 3 standard lengths, 21mm and 25mm and 31 mm.

The SAF should be mounted on a vertical-motion vibration contra-angle handpiece with a 0.4mm amplitude and vertical vibration of 3000 - 5000 OPM (oscillations per minute). The file is attached to the handpiece via a polypropylene shank.

Performance Data

Performance tests were carried out to evaluate the properties of the SAF. In all instances the SAF functioned as intended and results observed were as expected.

Substantial Equivalence

The SAF is substantially equivalent to the Quantec Series 2000 (manufactured by Tycom Dental), ProFile Series 29 (manufactured by Dentsply Tulsa Dental) and ProTaper (manufactured by Dentsply Tulsa Dental). The SAF has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the SAF and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrates that the SAF is as safe and effective as the Quantec Series 2000, ProFile Series 29 and the ProTaper. Thus, the SAF is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

Redent Nova Limited
C/O Mr. Jonathan S. Kahan
Hogan & Hartson, L.L.P.
Columbia Square
555 13th Street, Northwest
Washington, DC 20004

JAN 1 4 2010

Re: K092933
Trade/Device Name: Self Adjusting File (SAF)
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: December 31, 2009
Received: December 31, 2009

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K092933

Device Name:

The Self Adjusting File (SAF)

Indications for Use:

The Self Adjusting file (SAF) is a mechanically operated endodontic file to be used for cleaning and shaping of root canals, as part of the procedure of root canal treatment.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

RSBetz DDS for Dr. K.P. Mulay (Acting)
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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